

Remarks

I. Status of the Application and Claims

As originally filed, the present application had a total of 12 claims. These were all previously cancelled and replaced with claims 13-22. New claims 23-26 were added in a previous Response filed by Applicant. Thus, the claims now pending are claims 13-26.

II. The Amendments

Claim 13 and 23 were amended in paragraph a)1) to refer to "an" Enterobacteriaceae family rather than "the" Enterobacteriaceae family. This amendment was made to comply with the Examiner's suggestion on page 2 of the Office Action, item 3.

The transition in the second line of claim 15 was changed from "comprises" to "consists of."

Claim 23 was amended to remove underlining under the comma in paragraph a)iii). The replacement comma is still underlined but, in accordance with the rules of the PTO, this has been done to indicate the addition of replacement text. The underlining will not be present when the claim is rewritten in clean form.

One of the bacterial strains recited in claim 25 was deleted and the name of a second strain was corrected.

The amendments do not add new matter to the application and their entry is therefore respectfully requested.

III. Claim Objections

On pages 2 and 3 of the Office Action, the Examiner makes several objections to claims. These appear in items 3-6. Below, Applicant responds to each objection.

A. Response to Item 3

In item 3, the Examiner objects to claims 13 and 23 because of the use of the article "the" rather than "an." In response, Applicant has amended these claims in compliance with the

suggestion of the Examiner. Since there are no other rejections or objections for claim 13, it is respectfully submitted that this claim should now be allowable.

B. Response to Item 4

In item 4, the Examiner objects to claims 15 and 17 as failing to properly narrow the claim that they depend from. In response, claim 15 has been amended to change its transitional phrase from "comprises" to "consists of." In light of this amendment, it is submitted that the Examiner's objection has been overcome.

With respect to claim 17, Applicant believes that the Examiner is mistaken and that it already narrows claim 13. In this regard, it should be noted that claim 13 includes two ways for increasing the expression of a DNA sequence encoding the galactose-proton symporter protein. *i.e.*, by increasing the copy number of the DNA or by operably linking it to a promoter. Claim 17 limits the options to increasing copy number. Thus, claim 17 is narrower than claim 13.

Since there are no other objections or rejections for claims 15 and 17, Applicant believes that these claims should now be allowable.

C. Response to Item 5

In item 5, the Examiner objects to claim 23 because it has a comma with an underline. Applicant has amended the claim to eliminate this underlining, thereby obviating the Examiner's objection.

D. Response to Item 6

In item 6, the Examiner objects to claims 14, 16, 18 and 19 because they are dependent upon a claim that has received an objection, *i.e.*, claim 13. Since Applicant believes that the objection to claim 13 has been overcome, the objection to claims 14, 16, 18 and 19 should also be overcome. Since there are no other objections or rejections of these claims, Applicant submits that they should now be allowable.

The Rejections

I. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

On pages 4-5 of the Office Action, the Examiner rejects claims 21 and 22 under 35 USC § 112, second paragraph based upon the allegation that Applicant has offered conflicting arguments concerning the scope of these claims. In particular, the Examiner alleges that Applicant has argued that the various genes recited in the subparagraphs of the claims are limited to the exact species recited in the specification but has also offered the conflicting argument that, under the doctrine of equivalents, the claims encompass genes that are substantially the same as those recited.

In response, Applicant respectfully submits that the arguments that they have made do not conflict. As far as Applicant is aware, the doctrine of equivalents is always used in interpreting the scope of claims. This is true even if the claims are confined to a gene from a single species and even if the transitional phrase "consisting of" is used. This doctrine prevents a competitor from avoiding infringement by making a trivial change to a claimed invention. For example, in the case of a claim to a gene, it is well known that it is almost always possible to make one or more trivial mutations in a DNA sequence that do not affect the expression of the gene or the product made. For example, due to degeneracy in the genetic code, the third nucleotide position in a codon can often be changed without having any practical effect. Thus, without the doctrine of equivalents, most claims to specific genes would be essentially worthless.

Normally, the effect of the doctrine of equivalents is interpreted by courts during litigation and will depend upon a large number of factors. It is not usually something that comes up during prosecution and is not usually considered to make claims indefinite. If it did, essentially no claims could be allowed.

In light of the above considerations, Applicant submits that the genes recited in claims 21 and 22 are confined to the particular species in the specification but that the doctrine of equivalents still applies. It is also respectfully submitted that this should not be considered to render the claims indefinite.

II. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

On pages 4-5 of the Office Action, the Examiner rejects claim 25 under the first paragraph of 35 USC § 112. The Examiner alleges that the claim is not enabled because the bacterial strains recited in the claim have not been deposited.

In response, Applicant would like to point out that they have not made the bacterial strains that are included in claim 25. The bacteria merely represent various threonine-producing strains that could be used in connection with the claimed method for producing amino acids. As shown in Table 1, all of the strains now listed in the claims have been deposited at an appropriate patent depository.¹ Since all deposits are in the public domain and have been fully described in the references cited in the application (and listed in Table 1) Applicant does not believe that the present specification needs to be amended. However, they will be happy to do so if the Examiner still believes that this is necessary for there to be an allowance.

Table 1: Deposit Information for Claim 25

Bacterial Strain	Citing Reference	Site of Deposit	Deposit Number
H4581	US 4,996,147 (claimed in claim 1) (see also EP 0301572)	Fermentation Research Institute, Agency of Industrial Science and Technology Tsukuba-shi, Japan	BP-1411
VNIigenetika MG442	US 4,278,765 (claim 2)	Central Museum of Industrial Microorganisms of the All Union Research Institute of Genetics and Selection Moscow, Russia	CMIM B-1628
VNIigenetika M-1	US 4,321,325 (claim 1)	Central Museum of Industrial Microorganisms of the All Union Research Institute of Genetics and Selection Moscow, Russia	IIMIIB-1856
VNIigenetika M472T23	US 5,631,157 (claim 1)	American Type Culture Collection Manassas, Va.	ATTC 98082
BKIIM B-3996	US 5,175,107 (claim 7)	USSR Antibiotics Research Institute Moscow, Russia	Reg No. 1867
kat13	5,939,307 (claim 7)	Agricultural Research Service Culture Collection Peoria Ill.	NRRL B-21593
KCCM-10132	WO 00/09660	Korean Culture Center of Microorganisms Seoul, Korea	KCCM-10132

¹ Escherichia coli strain KY10935 was described in a scientific article. Since the strain should be capable of being produced using standard methodology, a deposit should not be required. Nevertheless, since a deposit number was not readily available, Applicant has removed this strain from claim 25 in an effort to expedite prosecution of the present application.

In light of the above considerations, Applicant submits that the enablement requirement of patentability has been met for claim 25. It is therefore respectfully requested that the present rejection of this claim under 35 USC § 112, first paragraph be withdrawn.

III. Rejection of Claims Under 35 U.S.C. § 102

On pages 7-8 of the Office Action, the Examiner makes two separate rejections under 35 USC § 102. In item 16, claims 23-24 and 26 are rejected as anticipated by Valle (US 2002/0155521) as evidenced by Blattner *et al.* (*Science* 277:1453-1474 (1997)). In item 17, these same claims are rejected under 35 USC § 102(a) as being anticipated by Hernandez-Montalvo *et al.* (*Biotechnol. Bioeng.* 83:687-694 (2003)) as evidenced by Blattner *et al.* and Lee *et al.* (*J. Bacteriol.* 185:5442-5451 (1997)). In a previous response, Applicant argued that their claims require that cells transport glucose by a PEP-dependent phosphotransferase (PTS) pathway whereas the references cited, particularly Valle reference and the Hernandez-Montalvo, only disclose an increase in gal-P transport in cells without a PTS pathway, *i.e.*, in PTS⁻ cells. The Examiner rejects this arguments stating that "any glucose transporter in the bacteria of Valle *et al.* or Hernandez-Montalvo *et al.* is encompassed by the term "PEP-dependent phosphotransferase pathway."

Applicant respectfully traverses this rejection.

As far as Applicant is aware, there is only one glucose transport pathway in cells that is termed the PEP-dependent phosphotransferase (PTS) pathway and this pathway does not include the galactose-proton symporter protein. This can be readily confirmed by looking at the figure on page 688 of the Hernandez-Montalvo reference. There is no justification for the Examiner concluding that more than one PTS pathway exists or that any glucose transporter can be part of the pathway. Not only is such a conclusion unsupported, but it actually appears to be contrary to the references themselves which, for example, clearly distinguish between the PTS pathway and the gal-P utilizing pathway.

The PTS pathway is not present in the cells disclosed in the references as should be clear from Applicant's previous arguments and from the fact that the references expressly refer to "PTS⁻" cells. Since Applicant's claims expressly require that the PTS pathway *is* present in the cells used in the process of claims 23, 24 and 26, there is not an anticipation.

Conclusion

In light of the amendments and discussion above, Applicant believes that all of the Examiner's rejections have been overcome. It is therefore respectfully requested that these rejections be withdrawn and that the claims now pending be allowed. Early notice to this effect is earnestly solicited.

If, in the opinion of the Examiner, a phone call would help to expedite the prosecution of this application, the Examiner is invited to call Applicant's undersigned attorney at (240) 683-6165.

Respectfully submitted,

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